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May 15, 2002

The Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: Comments on the Great Lakes Chemical Corporation's HPV Test Plan for Carbonic Acid, Oxydiethylene Diallyl Ester

Dear Administrator Whitman:

The following comments on the test plan by Great Lakes Chemical Corporation and PPG Industries, Inc.'s (hereafter referred to as GLCC) for the individual chemical carbonic acid, oxydiethylene diallyl ester are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than nine million Americans.

The GLCC has proposed a genetic toxicity test for chromosomal aberrations and "a 90-day repeated dose oral or dermal toxicity study" to examine subchronic toxicity and reproduction. We have serious concerns about these proposals, as we have had with past GLCC test plans.

The GLCC must specify whether the chromosomal aberration study will be conducted *in vivo* or *in vitro*. To demonstrate good faith and commitment to minimal animal protection principles outlined in the October 1999 Agreement among the EPA, industry, and health, animal protection, and environmental organizations, the GLCC should conduct the OECD TG 473 *in vitro* mammalian cytogenetic test for chromosomal damage. The October 1999 Agreement states, "Participants are encouraged to use *in vitro* genetic toxicity testing to generate any needed genetic toxicity screening data, unless known chemical properties preclude its use."

Additionally, it is not clear if the GLCC plans to conduct one or two repeat dose tests. Per the October 1999 Agreement, the GLCC should reconsider whether or not conducting this test is necessary, given the totality of what is known about diallyl diglycol carbonate. Adverse health effects of this chemical have been identified. A 1-percent solution can cause contact dermatitis in humans. The reported LD-50 values warrant a classification as toxic or moderately toxic by various international hazard classification systems. This chemical has already been tested for teratogenicity. An adequate repeat dose test has already been conducted. Enough information is available to characterize the potential risks of exposure to this chemical. However, if the GLCC decides to go forward with an animal test, it should conduct only one test with the most relevant route of exposure.

The 90-day repeat dose test is not part of the HPV program, and dermal toxicity testing is specifically excluded from the HPV program, as stated in the October 1999 Agreement. We recognize the fact that the GLCC's current proposal uses fewer animals than would be used were a separate reproductive toxicity study carried out. However, the 14- to 28-day repeat dose study that is part of the SIDS battery can also be used to evaluate reproductive toxicity and would further reduce animal suffering.

Thank you for your attention to these comments. I can be reached at 202-686-2210, ext. 302, or via e-mail at *ncardello@pcrm.org*. Correspondence may be sent to my attention to PCRM, 5100 Wisconsin Ave., N.W., Suite 400, Washington, DC 20016.

Sincerely,

Nicole Cardello, M.H.S.
Staff Scientist